

REMARKS

Reconsideration and withdrawal of the restriction and election requirements are respectfully requested in view of the remarks herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 67-96 are pending in the current application. Claims 67 and 68 have been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is respectfully submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amendments can be found throughout the specification and in the claims as originally filed.

Specifically, claims 67 and 68 have been amended to remove a definition of "X" which is unnecessary as the sulphamate group is specifically depicted in Formula IV.

II. RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS

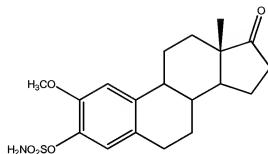
The March 14, 2008 Office Action required restriction from among the following:

- I. Claims 67 and 96, drawn to a method of inhibiting steroid sulphatase activity, classified in class 514, subclass 169+.
- II. Claims 68-95, drawn to a method of treating endocrine-dependent cancer, classified in class 514, subclass 169+.

Applicants elect, with traverse, the claims of Group I. Applicants note that Group I should actually include claims 69, 71, 73, 75, 77, 79, 81, 83, 85, 87, and 89, not merely claims 67 and 96 as indicated in the Office Action, and therefore request that at least all of claims 67, 69, 71, 73, 75, 77, 79, 81, 83, 85, 87, 89 and 96 be searched and examined. Applicants reserve the right to file divisional applications to non-elected subject matter.

The Office Action also required election of a single disclosed species.

Applicants elect, with traverse, the species 2-methoxy-EMATE (see p.15, paragraph 0331 of the specification as published):



In the event the restriction requirement is reconsidered as requested herein, and the claims of Groups I and II are rejoined, Applicants elect, with traverse, breast cancer.

It is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. (MPEP § 803) Second, searching the additional inventions must constitute an undue burden on the Examiner if restriction is not required. *Id.* The MPEP directs the Examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions.” *Id.*

The Office Action alleges that Groups I and II relate to two distinct inventions and do not encompass overlapping subject matter. The Office Action asserts that the inventions of Group I and II are distinct based on criteria listed in MPEP 806.05(j) as they “have a materially different function, i.e., inhibiting an enzyme *versus* treating a cancer, do not overlap, i.e., treating of endocrine dependent cancer is not of the same scope as inhibition of steroid sulphatase activity and they are not obvious variants”.

It is respectfully submitted that the present application relates to the use of novel steroid sulphatase inhibitors for treating tumors in endocrine-dependent tissues, especially breast cancer. The direct result of inhibiting STS activity is a reduction in *in situ* estrogen levels and hence the treatment of any cancers which are dependent on the endocrine system (support can be found throughout specification as published; specifically see p.1, paragraphs 0004, 0006, and 0109). Applicants’ claims are directed to, *inter alia*, a method of treating endocrine-dependent cancer by inhibiting oestrone sulphatase. Due to the direct relationship between inhibition of STS and endocrine-dependent cancers, unity of the invention, therefore exists.

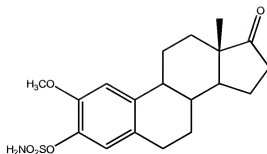
It is also respectfully submitted that the criteria listed in MPEP § 803 have not been met in this case, as no adequate showing has been made that an undue burden would be placed on the Examiner. The Office Action alleges that an undue burden would result from the search and examination of the claims if restriction were not required because of one or more of five separate reasons, including separate classification, divergent subject matter, different fields of search, differences in prior art that would be anticipatory to each Group, and the inventions would likely raise different non-prior art issues. Applicants respectfully submit that such a statement does not meet the burden placed on the Examiner for proving that restriction is required.

The Examiner has not, in fact, provided any definitive statement as to why an undue burden would result from the search and examination of the full set of claims. Instead, the Examiner provides a generic list of potential reasons for such a burden to exist, without any discussion or details as to how the generic categories apply to the present claims. Indeed, the Office Action fails to consider that Groups I and II are identically classified in class 514, subclass 169+.

Furthermore, in contrast to the Office Action's assertions, the claims of the present application are linked as a single, common invention: the use of a compound of formula IV as a steroid sulphatase inhibitor. That the claims relate to methods of inhibiting steroid sulphatase activity by administering a compound of formula IV and methods of treating endocrine-dependent cancers by administering the same compound of formula IV is not indicative of distinctness. Rather, search and examination of the claims of the present invention would necessarily be co-extensive by virtue of the interrelatedness present in the pending claims. That is, the search and examination of the claims of Group I would necessarily encompass the claims of Group II and as such, a search would necessarily include any reference to the compounds of formula IV. Any supplemental searching would therefore be minimal and insufficient to rise to the level of an undue burden.

Therefore, the restriction requirement is improper because it does not satisfy both requirements for restriction and should be withdrawn. In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested.

Turning now to the species election, as stated previously, Applicants elect, with traverse, 2-methoxy-EMATE, a compound of formula:



It is understood that the Examiner can broaden the search to include other species, e.g., upon determining that a species is allowable, or when there is a relationship among the species and/or the number of species is not too great. The Examiner is respectfully requested to review M.P.E.P. § 808.01(a), which states that “where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention” is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In the instant case, there is a disclosure of relationship between the claimed species. Applicants respectfully submit that claims 67, 69, 71, 73, 75, 77, 79, 81, 83, 85, 87, 89, and 96 read on the compounds of formula IV. Applicants’ claims of Groups I are all directed to the methods of administering a compound of formula IV. Consequently, there is a disclosed relationship between the species as they are all related to the steroid sulphotase inhibitor of formula IV. It is respectfully submitted that any search for 2-methoxy-EMATE will certainly encompass references to the compounds of the Group I claims. Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine the compounds of formula IV, as a search for 2-methoxy-EMATE will certainly encompass references for the compounds of the Group I claims. Thus, Applicants respectfully assert that a clear relationship exists between the species identified in the Office Action, such that the species election is not proper.

In view of the above, reconsideration and withdrawal of the election of species requirement are requested.

In summary, enforcing the present restriction and election of species requirements would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term

may result in any divisional applications filed). Restriction and election have not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made. Indeed, the search and examination of both Groups would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner, especially as the claims of both Groups have identical classifications. Furthermore, the election requirement has not been shown to be proper, especially since there is an overlap in scope. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested.

CONCLUSION

In view of the remarks herein, reconsideration and withdrawal of the restriction requirement are requested. Early and favorable consideration of the application on the merits, and early allowance of the application are earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: /Angela M. Collison/
Thomas J. Kowalski
Reg. No. 32,147
Angela M. Collison
Reg. No. 51,107
Tel. No. (212) 588-0800
Fax No. (212) 588-0500